Logistical Challenges of IND Use in an Operational Setting:

Operations Enduring/Iraqi Freedom

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SMART-IND Team

Background

- April, 2000 – ASD(HA) directs MRMC to prepare contingency protocol for anthrax vaccine post-exposure prophylaxis
- Immediately after 9/11/01 – ASD(HA) directs MRMC to develop 3 tiers of protocols:
  - Tier 1 includes:
    - Bot Toxoid
    - VIG-IM
    - Bot Antitoxins
    - Anthrax post-exposure
    - Cell culture vaccinia
  - Later modified to:
    - vaccinia 1:1 and 1:5
    - Cidofovir – vaccinia rxn or smallpox
- ~9 months until first protocol to FDA

Background

- SMART-IND
  - Team established fall 2003 by OTSG memo
  - Pulled to USAMMDA December 8, 2003
- 3 groups in original 19 member team
  - ConOps
  - Training
  - Protocol
- Team departure scheduled 16 Feb 03
- In Kuwait 2/24 – 5/4/03

Mission

- Assist the Coalition Forces Land Component Command (CFLCC) Surgeon to provide countermeasures to the threat of botulinum toxin release in the Central Command (CENTCOM) area of operations.

Deploying Team Members

PERSONNEL	RANK	INSTITUTE
• 3 ID Physicians	COLs	WRAIR
• 1 ID Physician	LTC	WRAIR
• 1 PM Physician	LTC	USAMRIID
• 1 Protocol Nurse	CPT	USAMRIID
• 2 Combat Medics	E6/E5	WRAIR/ICD
• 1 Med Supply NCO	E5	WRAIR

Telephone Communications

- All team members provided cell phones
  - Useful for US commo
  - Worthless for in-theater commo
- 4 secure Iridium satellite phones
  - Periodic use when out of cell phone range
  - When secure, transmission garbled
- Team purchased 2 local cell phones

Email Communications

- All team members provided Panasonic CF-72 laptops ("toughbooks")
  - Configured in advance of deployment
  - Requirement for secure communications
    - Needed separate computer
    - Difficulty communicating to Fort Detrick
  - All team members need to be connected

Commo Lessons Learned

- Know in-theater commo in advance
- Bring dedicated SIPR computers
- Ensure secure commo via STU and secure email in CONUS
- Have IT specialist as a team member

Product Accountability/Transport/Storage

- Finding product at airport
- Log didn't want ownership for accountability or temp documentation
- Lack of storage site/power source for vaxicools
  - Good relations with warehouse personnel
- Vehicle requirement for transport
  - SUVs
  - Presentation to the CARB
- Car cigarette lighter hook-up
- Accountability forms
- Vaxicools good for transport, but fixed fridges/freezers preferable – one never found

Lessons Learned

- Advanced party determine storage sites
  - Dedicated freezers/fridges
  - Dedicated storage site
- Dedicated log team member
- Vet accountability forms in advance
- Be nice to the locals

Transportation

- Vehicles loaned by CFLCC
  - 06 signature required
- Convoy requirements
  - 2 vehicles
  - 1 weapon per vehicle
  - 1 cell phone per vehicle
- Hazardous driving
  - Concern about snipers
  - Locals don't follow traffic rules
  - Rollovers/Sandstorms
- Travel by air difficult
  - Space available
  - Air evacs have precedence
  - Inability to return to Comfort

Lessons Learned

- Dedicated vehicles preferable
- Extra people needed for convoys
- Rank improves independence
- Can't rely on air transport
  - Even with personal connections

Protocol Training

- Variety of venues
  - Comfort/various tents/cafeteria
- Challenges
  - Lack of electricity (generator blew)
  - Computer incompatibility (stick)
  - 110 vs 220 volts
  - Lack of microphones/screens
  - Requirement for multiple visits to train all personnel and obtain GCP paperwork
- Final protocol versions not complete before team deployed
- Briefing materials, CRFs, and IB packets didn't arrive until after training had begun
  - Much copying required in-theater
  - Limited copiers and paper
  - Fast laser printer saved us
- Enrollment logs, sign-in rosters, training rosters – developed in-theater

GCP Training

- Stateside solution did not fit in-theater constraints
- Eduneering – web site established for GCP training
  - Problem – access to internet limited in-theater
- Training completed primarily on paper
  - IND team faxed registration forms and completion certificates to the contractor

Lessons Learned

- Develop baseline GCP course that IND team could present
- Focus training only on protocol participants, not DoD-wide
- Be prepared for multiple training venues
- Accommodate patient care schedule of training sites to capture all necessary personnel by leaving 1-2 team members on-site until training completed/documented
- Be prepared for 110/220 volt and lack of electricity
- Have completed protocols/forms in advance
  - Have investigator packets assembled in advance
- Be flexible

Forms/Regulatory Files

- On-site form assembly
- Lack of time for vetting pre-deployment
  - In-theater modifications or use of earlier versions
- On-site assembly of regulatory file
- Difficult to capture all email protocol correspondence
- Potential for loss of original regulatory files/CRFs
  - Unit rotation
  - Lack of functioning photocopiers

Lessons Learned

- Vet all forms before use needed
- Bring completed (to the extent possible) regulatory files
- Triplicate forms useful
- Designate a single individual to correspond with sponsor/IRB

Accomplisments

- Botulinum Toxin
  - Developed bot response plan
  - Developed/distributed wallet bot recognition cards
  - Distributed bot training material
  - Established treatment facilities at 3 CSHes and the USNS Comfort
  - Trained 110 Army/Navy medical personnel to function as EBAT study investigators
  - Trained 865th CSH on bot MASCAL procedures
  - Offered vaccination/immune globulin to 64 at-risk personnel
    - 20 enrolled for botulinum toxoid
    - 6 enrolled for immune globulin
- Other Infectious Diseases
  - Trained 865th CSH investigators on VIG
  - Drafted SARS response plan
  - Established contacts with local laboratories for SARS diagnostics
  - Drafted biological warfare response plan
  - Served as consultants on malaria chemoprophylaxis policy

Bottom Line

- We accomplished what we were sent to do
  - Established bot antitoxin capability
  - Trained the appropriate personnel and documented the training
  - Maintained product accountability and cold chain

Final Lesson Learned

- Success requires support and buy-in of:
  - Team in the rear
    - MRMC Command
    - Non-deployed IND team
    - USAMMDA
    - Med Log
    - HSRRB
  - In-theater commanders
    - CFLCC Surgeon
    - 75th XTF
    - Combat Support Hospitals and clinics
  - In-theater medical personnel
- Incredibly manpower intensive to accomplish